IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 18-336-VAC-MPT
JUBILANT LIFE SCIENCES LIMITED, JUBILANT PHARMA LIMITED, JUBILANT GENERICS LIMITED, JUBILANT LIFE SCIENCES (USA) INC., and JUBILANT CADISTA PHARMACEUTICALS INC.,	)	JURY TRIAL DEMANDED
Defendants.	)	

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Jubilant Life Sciences Limited ("Jubilant Life Sciences"), Jubilant Pharma Limited ("Jubilant Pharma"), Jubilant Generics Limited ("Jubilant Generics"), Jubilant Life Sciences (USA) Inc. ("Jubilant USA"), and Jubilant Cadista Pharmaceuticals Inc. ("Jubilant Cadista") (collectively, "Jubilant"), by way of Answer to Plaintiffs' Complaint, state as follows:

Jubilant denies each and every allegation contained in the Complaint, except as specifically admitted or explained herein. To the extent that the headings or any other non-numbered statements in the Complaint contain any allegations, Jubilant denies each and every such allegation.

THE PARTIES

1. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of Plaintiffs' Complaint, and therefore denies all such allegations.

2. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of Plaintiffs' Complaint, and therefore denies all such allegations.

3. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of Plaintiffs' Complaint, and therefore denies all such allegations. To the extent an answer is required, Jubilant admits the following: (1) the electronic version of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists "Sunovion Pharmaceuticals Inc." as the applicant for New Drug Application ("NDA") No. 022416 for APTIOM® brand eslicarbazepine acetate oral tablets, in 200 mg, 400 mg, 600 mg and 800 mg dosage strength; (2) according to the Prescribing Information for APTIOM® brand eslicarbazepine acetate tablets, APTIOM is indicated for treating partial-onset seizures in patients 4 years of age and older; and (3) U.S. Patent Nos. 8,372,431; 9,566,244; 9,206,135; 9,643,929; 9,750,747 and 9,763,954 are listed in the Orange Book in connection with NDA No. 022416.

4. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiffs' Complaint, and therefore denies all such allegations.

5. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Life Sciences is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida-201301, Uttar Pradesh, India.

6. Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista, which are wholly owned subsidiaries of Jubilant Pharma, which is in turn a subsidiary of Jubilant

Life Sciences, are in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products throughout the United States, including the State of Delaware. Jubilant denies all other remaining allegations in Paragraph 6.

7. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Pharma is a corporation organized and existing under the laws of Singapore, with its principal place of business at 6 Temasek Boulevard, #20-06 Suntec City Tower Four, Singapore 038986.

8. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Pharma is a subsidiary of Jubilant Life Sciences.

9. Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista, which are wholly owned subsidiaries of Jubilant Pharma, are in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products throughout the United States, including the State of Delaware. Jubilant denies all other remaining allegations in Paragraph 9.

10. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida –201301, Uttar Pradesh, India.

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is a wholly-owned subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is in the business of, *inter alia*, manufacturing, marketing, and selling generic pharmaceutical products the United States. Jubilant denies all other remaining allegations in Paragraph 12.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 790 Township Line Road, Suite 175, Yardley, Pennsylvania 19067.

14. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant USA is a subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

15. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that: (1) Jubilant USA is in the business of, *inter alia*, marketing and selling generic pharmaceutical products in the United States; and (2) Jubilant USA is the marketing office for Jubilant Life Sciences, Jubilant Pharma, and Jubilant Generics in the United States. Jubilant denies all other remaining allegations in Paragraph 15.

16. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is a corporation organized and existing under the laws of Delaware, with its principal place of business at 207 Kiley Drive, Salisbury, Maryland 21801.

17. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is a subsidiary of Jubilant Pharma, which is a subsidiary of Jubilant Life Sciences.

18. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is in the business of, *inter alia*, marketing and selling generic pharmaceutical products in the United States. Jubilant denies all other remaining allegations in Paragraph 18.

19. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 19.

20. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 211219, Jubilant Cadista will distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211219 ("Jubilant's ANDA Product") in the United States. Jubilant denies all other remaining allegations in Paragraph 20.

NATURE OF THE ACTION

21. Jubilant admits that Plaintiffs' Complaint purports to be an action for patent infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), 9,750,747 ("the '747 patent), and 9,763,954 ("the '954 patent) (collectively, "patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq*., and in particular under 35 U.S.C. § 271. Jubilant admits that it filed ANDA No. 211219 under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic version of

Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit. Jubilant denies all other remaining allegations in Paragraph 21.

JURISDICTION AND VENUE

22. Jubilant repeats and incorporates by reference each of its answers to the foregoing paragraphs as if fully set forth herein.

23. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that Plaintiffs' Complaint purports that this action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but denies all other remaining allegations in Paragraph 23.

24. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant admits that subject matter jurisdiction over Plaintiffs' patent infringement claims is proper.

25. This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Jubilant does not contest venue for this particular action.

26. This Paragraph contains legal conclusions to which no answer is required. Jubilant Life Sciences does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 26.

27. This Paragraph contains legal conclusions to which no answer is required. Jubilant Pharma does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 27.

28. This Paragraph contains legal conclusions to which no answer is required. Jubilant Generics does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 28.

29. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant USA is a corporation organized and existing under the laws of Delaware. Jubilant USA does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 29.

30. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Cadista is a corporation organized and existing under the laws of Delaware. Jubilant Cadista does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 30.

31. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant USA admits that Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808 is an authorized U.S. agent of Jubilant. Jubilant denies all other remaining allegations in Paragraph 31.

32. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant Cadista admits that Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808 is an authorized U.S. agent of Jubilant. Jubilant denies all other remaining allegations in Paragraph 32.

33. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 33.

34. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 34.

35. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics seeks approval for ANDA No. 211219 to manufacture, import, market, and/or sell Jubilant's ANDA Product upon approval; and that Jubilant Cadista and Jubilant USA are subsidiaries of Jubilant Pharma in the United States, which is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 35.

36. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is involved in preparing, filing and maintaining ANDA No. 211219; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of Jubilant Pharma in the United States, which is in turn a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 36.

37. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant Generics is involved in the drafting, submission, approval and maintenance of ANDA No. 211219; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of Jubilant Pharma in the United States, which is in turn a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 37.

38. Jubilant does not contest personal jurisdiction in this particular action but denies all allegations in Paragraph 38.

39. Jubilant admits that following FDA approval of ANDA No. 211219, Jubilant Cadista will market, distribute, and sell Jubilant's ANDA Product described in ANDA No. 211219 in the United States. Jubilant denies all other remaining allegations in Paragraph 39.

40. This Paragraph contains legal conclusions to which no answer is required. Jubilant does not contest personal jurisdiction in this particular action. To the extent an answer is required, Jubilant admits that Jubilant Generics, Jubilant USA, and Jubilant Cadista develop, manufacture or market generic prescription drug products in the United States, including in Delaware; and that Jubilant Generics, Jubilant USA, and Jubilant Cadista are subsidiaries of Jubilant Pharma in the United States, which is a subsidiary of Jubilant Life Sciences. Jubilant denies all other remaining allegations in Paragraph 40.

41. Jubilant does not contest personal jurisdiction in this particular action. Jubilant denies all other remaining allegations in Paragraph 41.

FACTUAL BACKGROUND

The NDA

42. Jubilant admits that according to the electronic version of the FDA's Orange Book publication, "Sunovion" is identified as the applicant for NDA No. 022416 for APTIOM® brand eslicarbazepine acetate tablets, in 200 mg, 400 mg, 600 mg, and 800 mg dosage strengths. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 42, and therefore denies same.

43. Jubilant admits that according to the NDA Approval letter dated November 8, 2013 for NDA No. 022416, the FDA stated, "This new drug application provides for the use of Aptiom (eslicarbazepine acetate) 200 mg, 400 mg, 600 mg, and 800 mg tablets for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years and older."

Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 43, and therefore denies same.

44. Jubilant admits that according to the Supplement Approval letter dated August 27, 2015 for NDA No. 022416/S-001, the FDA stated, "This 'Prior Approval' supplemental new drug application provides for the addition of the indication for monotherapy treatment of partial-onset seizures in adults." Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 44, and therefore denies same.

45. Jubilant admits that according to the Supplement Approval letter dated September 13, 2017 for NDA No. 22416/S-009, the FDA stated that "the indication for Aptiom is being expanded to include pediatric patients 4 years of age and older." Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 45, and therefore denies same.

46. Jubilant admits that according to the Prescribing Information for APTIOM® brand eslicarbazepine acetate tablets, APTIOM® is indicated for the treatment of partial onset seizures in patients 4 years of age and older, and eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patents-in-Suit

47. Jubilant admits that according to the online records of the United States Patent and Trademark Office ("USPTO"): (1) the title of the '431 patent is "Pharmaceutical composition comprising licarbazepine acetate," (2) the '431 patent was issued by the USPTO on February 12, 2013, and (3) a copy of the '431 patent was attached to the Complaint.

48. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '431 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '431 patent issued from application no. 12/257,240; (3) according to the online records of the USPTO an assignment by Teofilo Cardoso de Vasconcelos, Ricardo Jorge dos Santos Lima, and Rui Cerdeira de Campos Costa to Bial-Portela & C.A., S.A. for application no. 12/257,240 is recorded at reel/frame 022072/0964 by a conveyance executed on December 18, 2008 and recorded on January 7, 2009; and (4) the Orange Book lists the expiration date of the '431 patent as April 17, 2030. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 48, and therefore denies same.

49. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '431 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

50. Jubilant admits that according to the online records of the USPTO: (1) the title of the '135 patent is "Asymmetric catalytic reduction of oxcarbazepine," (2) the '135 patent was issued by the USPTO on December 8, 2015, and (3) a copy of the '135 patent was attached to the Complaint.

51. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '135 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '135 patent issued from application no. 13/651,844; (3) according to the online records of the USPTO an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 13/651,844 is recorded at reel/frame 029941/0478 by a conveyance executed on March 13,

2008 and recorded on March 7, 2013; (4) the recorded document at reel/frame 029941/0478 shows an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 11/997,104, of which application no. 13/651,844 is a continuation; and (5) the Orange Book lists the expiration date of the '135 patent as April 21, 2026. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 51, and therefore denies same.

52. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '135 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

53. Jubilant admits that according to the online records of the USPTO: (1) the title of the '244 patent is "Pharmaceutical composition comprising licarbazepine acetate," (2) the '244 patent was issued by the USPTO on February 14, 2017, and (3) a copy of the '244 patent was attached to the Complaint.

54. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '244 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '244 patent issued from application no. 14/108,615; (3) according to the online records of the USPTO an assignment by Teofilo Cardoso de Vasconcelos, Ricardo Jorge dos Santos Lima, and Rui Cerdeira de Campos Costa to Bial-Portela & C.A., S.A. for application no. 14/108,615 is recorded at reel/frame 031799/0632 by a conveyance executed on December 18, 2008 and recorded on December 17, 2013; (4) the recorded document at reel/frame 031799/0632 shows an assignment by Teofilo Cardoso de Vasconcelos, Ricardo Jorge dos Santos Lima, and Rui Cerdeira de Campos Costa to Bial-Portela & C.A., S.A. for application no. 12/257,240, of which application no. 14/108,615 is a continuation; and (5) the

Orange Book lists the expiration date of the ’244 patent as October 23, 2028. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 54, and therefore denies same.

55. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the ‘244 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

56. Jubilant admits that according to the online records of the USPTO: (1) the title of the ‘929 patent is “Asymmetric catalytic reduction of oxcarbazepine,” (2) the ‘929 patent was issued by the USPTO on May 9, 2017, and (3) a copy of the ‘929 patent was attached to the Complaint.

57. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the ‘929 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the ‘929 patent is a continuation of application no. 13/651,844; (3) according to the online records of the USPTO an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 13/651,844 is recorded at reel/frame 029941/0478 by a conveyance executed on March 13, 2008 and recorded on March 7, 2013; (4) the recorded document at reel/frame 029941/0478 shows an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 11/997,104, of which application no. 13/651,844 is a continuation; and (5) the Orange Book lists the expiration date of the ’929 patent as April 21, 2026. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 57, and therefore denies same.

58. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '929 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

59. Jubilant admits that according to the online records of the USPTO: (1) the title of the '747 patent is "Treatments involving eslicarbazepine acetate or eslicarbazepine," (2) the '747 patent was issued by the USPTO on September 5, 2017, and (3) a copy of the '747 patent was attached to the Complaint.

60. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '747 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '747 patent issued from application no. 14/240,847; (3) according to the online records of the USPTO an assignment by Patricio Manuel Vieira Araujo Soares Da Silva to Bial-Portela & C.A., S.A. for application no. 14/240,847 is recorded at reel/frame 032991/0598 by a conveyance executed on March 2, 2014 and recorded on May 29, 2014; (4) according to the online records of the USPTO a corrective assignment to correct the spelling of the assignee's name is recorded at reel/frame 033433/0809 by a conveyance executed on March 2, 2014 and recorded on July 29, 2014; and (5) the Orange Book lists the expiration date of the '747 patent as August 24, 2032. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 60, and therefore denies same.

61. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '747 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

62. Jubilant admits that according to the online records of the United States Patent and Trademark Office ("USPTO"): (1) the title of the '954 patent is "Therapeutical uses of eslicarbazepine," (2) the '954 patent was issued by the USPTO on September 19, 2017, and (3) a copy of the '954 patent was attached to the Complaint.

63. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits the following: (1) the '954 patent is assigned on its face to Bial-Portela & C.A., S.A.; (2) the '954 patent issued from application no. 14/134,843 and claims priority to application no. 12/522,535; (3) according to the online records of the USPTO an assignment by Patricio Manuel Vieira Ara Soares Da Silva to Bial-Portela & C.A., S.A. for application no. 14/134,843 is recorded at reel/frame 031840/0314 by a conveyance executed on September 1, 2009 and recorded on December 23, 2013; and (4) the Orange Book lists the expiration date of the '954 patent as September 13, 2028. Jubilant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 63, and therefore denies same.

64. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that the '954 patent is listed in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

The ANDA

65. Jubilant admits that Jubilant has submitted to the FDA ANDA No. 211219 ("Jubilant's ANDA Product") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms. Jubilant also admits that Jubilant's ANDA refers to and relies upon the APTIOM® NDA and contains data that,

according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 65.

66. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA No. 211219 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), asserting that the claims of the patents-in-suit are invalid, unenforceable, and/or would not be infringed by Jubilant's ANDA Product.

67. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Plaintiffs received a letter sent by Jubilant, dated January 15, 2018, for ANDA No. 211219 ("Jubilant's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. The Jubilant Notice Letter stated that Jubilant had filed ANDA No. 211219, seeking approval to market Jubilant's ANDA Product prior to the expiration of the patents-in-suit.

68. Jubilant admits that Plaintiffs filed a complaint against Jubilant on or about March 1, 2018 following receipt of Jubilant's January 15, 2018 Notice Letter.

COUNT I

(INFRINGEMENT OF THE '431 PATENT UNDER 35 U.S.C. § 271(e)(2))

69. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

70. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. §

314.94(a)(12)(i)(A)(4) that the claims of the '431 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 70.

71. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '431 patent are invalid, unenforceable, and/or not infringed.

72. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 72.

73. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 73.

74. Jubilant denies the allegations in Paragraph 74.

75. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 75.

76. Jubilant denies the allegations in Paragraph 76.

77. Jubilant denies the allegations in Paragraph 77.

78. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA

seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 78.

79. Jubilant denies the allegations in Paragraph 79.

COUNT II

(INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271(e)(2))

80. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

81. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the claims of the '135 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 81.

82. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '135 patent are invalid, unenforceable, and/or not infringed.

83. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 83.

84. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 84.

85. Jubilant denies the allegations in Paragraph 85.

86. Jubilant denies the allegations in Paragraph 86.

87. Jubilant admits that it was aware of the '135 patent but denies the remaining allegations in Paragraph 87.

88. Jubilant denies the allegations in Paragraph 88.

89. Jubilant admits that it was aware of the '135 patent but denies the remaining allegations in Paragraph 89.

90. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 90.

91. Jubilant denies the allegations in Paragraph 91.

92. Jubilant denies the allegations in Paragraph 92.

93. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 93.

94. Jubilant denies the allegations in Paragraph 94.

COUNT III

(INFRINGEMENT OF THE '244 PATENT UNDER 35 U.S.C. § 271(e)(2))

95. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

96. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the claims of the '244 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 96.

97. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '244 patent are invalid, unenforceable, and/or not infringed.

98. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 98.

99. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 99.

100. Jubilant denies the allegations in Paragraph 100.

101. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA

seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 101.

102. Jubilant denies the allegations in Paragraph 102.

103. Jubilant denies the allegations in Paragraph 103.

104. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 104.

105. Jubilant denies the allegations in Paragraph 105.

COUNT IV

(INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(e)(2))

106. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

107. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the claims of the '929 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 107.

108. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to

21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '929 patent are invalid, unenforceable, and/or not infringed.

109. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 109.

110. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 110.

111. Jubilant denies the allegations in Paragraph 111.

112. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 112.

113. Jubilant denies the allegations in Paragraph 113.

114. Jubilant denies the allegations in Paragraph 114.

115. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 115.

116. Jubilant denies the allegations in Paragraph 116.

COUNT V

(INFRINGEMENT OF THE '747 PATENT UNDER 35 U.S.C. § 271(e)(2))

117. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

118. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the claims of the '747 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 118.

119. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '747 patent are invalid, unenforceable, and/or not infringed.

120. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 120.

121. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 121.

122. Jubilant denies the allegations in Paragraph 122.

123. Jubilant denies the allegations in Paragraph 123.

124. Jubilant admits that it was aware of the '747 patent but denies the remaining allegations in Paragraph 124.

125. Jubilant denies the allegations in Paragraph 125.

126. Jubilant admits that it was aware of the '747 patent but denies the remaining allegations in Paragraph 126.

127. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 127.

128. Jubilant denies the allegations in Paragraph 128.

129. Jubilant denies the allegations in Paragraph 129.

130. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 130.

131. Jubilant denies the allegations in Paragraph 131.

COUNT VI

(INFRINGEMENT OF THE '954 PATENT UNDER 35 U.S.C. § 271(e)(2))

132. Jubilant repeats and incorporates by reference each of its answers to the foregoing Paragraphs as if fully set forth herein.

133. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed ANDA No. 211219 with the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the claims of the '954 patent are invalid, unenforceable, and/or not infringed. Jubilant denies all other remaining allegations in Paragraph 133.

134. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '954 patent are invalid, unenforceable, and/or not infringed.

135. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant admits that Jubilant's ANDA filed with FDA refers to and relies upon the APTIOM® NDA and contains data that, according to Jubilant, demonstrates the bioequivalence of Jubilant's ANDA Product and APTIOM®. Jubilant denies all other remaining allegations in Paragraph 135.

136. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant denies the allegations in Paragraph 136.

137. Jubilant denies the allegations in Paragraph 137.

138. Jubilant denies the allegations in Paragraph 138.

139. Jubilant admits that it was aware of the '954 patent but denies the remaining allegations in Paragraph 139.

140. Jubilant denies the allegations in Paragraph 140.

141. Jubilant admits that it was aware of the '954 patent but denies the remaining allegations in Paragraph 141.

142. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 142.

143. Jubilant denies the allegations in Paragraph 143.

144. Jubilant denies the allegations in Paragraph 144.

145. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Jubilant submitted the Jubilant ANDA No. 211219 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Jubilant's ANDA Product. Jubilant denies the remaining allegations in Paragraph 145.

146. Jubilant denies the allegations in Paragraph 146.

REQUEST FOR RELIEF

Jubilant denies that Plaintiffs are entitled to any relief. Jubilant requests that the Court dismiss Plaintiffs' Complaint with prejudice, enter judgment in favor of Jubilant, award Jubilant its reasonable attorneys' fees and costs incurred in defending this suit, and award Jubilant such other relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

Jubilant alleges and asserts the following affirmative defenses in response to the allegations in the Complaint. Jubilant reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

FIRST AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '431 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '431 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '431 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '431 patent.

FOURTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '135 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '135 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

SIXTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '135 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '135 patent.

SEVENTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '244 patent, either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '244 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

NINETH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '244 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '244 patent.

TENTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed,

infringe, either directly or indirectly, any valid and enforceable claim of the '929 patent, either literally or under the doctrine of equivalents.

ELEVENTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '929 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

TWELVETH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '929 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '929 patent.

THIRTEENTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '747 patent, either literally or under the doctrine of equivalents.

FOURTEENTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '747 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

FIFTEENTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '747 patent by reason of actions taken and statements

made by the applicant for that patent to the PTO during prosecution of the application that lead to the '747 patent.

SIXTEENTH AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)

The manufacture, use or sale of the eslicarbazepine acetate product that is the subject of ANDA No. 211219 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '954 patent, either literally or under the doctrine of equivalents.

SEVENTEENTH AFFIRMATIVE DEFENSE (INVALIDITY)

The claims of the '954 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

EIGHTEENTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)

Plaintiffs are estopped and/or precluded from asserting that the product described in Jubilant's ANDA No. 211219 infringes the '954 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '954 patent.

NINETEENTH AFFIRMATIVE DEFENSE (NO WILLFUL INFRINGEMENT)

Plaintiff's claims for enhanced damages, if any, and an award of fees and costs against Jubilant have no basis in fact or law and should be denied.

TWENTIETH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSE

Jubilant reserves the right to assert additional affirmative defenses that may be developed through discovery, or otherwise, in this action.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs, Defendants Jubilant state as follows, without admitting any allegations of the Complaint not expressly admitted and without assuming the burden when such burden would otherwise be on Plaintiffs/Counterclaim-Defendants.

PARTIES

1. Jubilant Life Sciences is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida-201301, Uttar Pradesh, India.

2. Jubilant Pharma is a corporation organized and existing under the laws of Singapore, with its principal place of business at 6 Temasek Boulevard, #20-06 Suntec City Tower Four, Singapore 038986.

3. Jubilant Generics is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida –201301, Uttar Pradesh, India.

4. Jubilant USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 790 Township Line Road, Suite 175, Yardley, Pennsylvania 19067.

5. Jubilant Cadista is a corporation organized and existing under the laws of Delaware, with its principal place of business at 207 Kiley Drive, Salisbury, Maryland 21801.

6. Upon information and belief, Plaintiff BIAL - PORTELA & CA S.A. ("BIAL - PORTELA") is a company organized and existing under the laws of Portugal, with its

principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-455 Trofa, Portugal.

7. Upon information and belief, Plaintiff BIAL - HOLDING, S.A. ("BIAL - HOLDING") is a corporation organized and existing under the laws of Portugal, with its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-365 Trofa, Portugal.

8. Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

JURISDICTION AND VENUE

9. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

11. Plaintiffs/Counterclaim-Defendants BIAL - PORTELA, BIAL - HOLDING, and Sunovion (collectively, "Bial") are subject to personal jurisdiction in this Judicial District because Plaintiffs subjected themselves to the jurisdiction of this Court by filing their Complaint here. Plaintiffs Bial are also subject to personal jurisdiction in this Judicial District because: (i) Sunovion sells products here, including the APTIOM® product that is the subject of this case, (ii) BIAL - PORTELA regularly practices business here, (iii) BIAL - HOLDING regularly practices business here, and (iv) Plaintiffs Bial have purposefully availed themselves of the benefits of jurisdiction in the State of Delaware.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendants' choice of forum in filing its Complaint against Jubilant here.

13. As a consequence of Plaintiffs/Counterclaim-Defendants' Complaint against Jubilant, there is now an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the patents-in-suit.

THE CONTROVERSY

14. The United States Patent and Trademark Office ("USPTO") issued the '431 patent on February 12, 2013, naming BIAL - PORTELA as the assignee on the face of the patent.

15. Upon information and belief, BIAL - PORTELA is the owner of the '431 patent based on an assignment by Teofilo Cardoso de Vasconcelos, Ricardo Jorge dos Santos Lima, and Rui Cerdeira de Campos Costa to Bial-Portela & C.A., S.A. for application no. 12/257,240 recorded at reel/frame 022072/0964 by a conveyance executed on December 18, 2008 and recorded on January 7, 2009.

16. The USPTO issued the '135 patent on December 8, 2015, naming BIAL - PORTELA as the assignee on the face of the patent.

17. Upon information and belief, BIAL - PORTELA is the owner of the '135 patent based on an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 11/997,104 recorded at reel/frame 029941/0478 by a conveyance executed on March 13, 2008 and recorded on March 7, 2013.

18. The USPTO issued the '244 patent on February 14, 2017, naming BIAL - PORTELA as the assignee on the face of the patent.

19. Upon information and belief, BIAL - PORTELA is the owner of the '244 patent based on an assignment by Teofilo Cardoso de Vasconcelos, Ricardo Jorge dos Santos Lima, and Rui Cerdeira de Campos Costa to Bial-Portela & C.A., S.A. for application no. 12/257,240 recorded at reel/frame 031799/0632 by a conveyance executed on December 18, 2008 and recorded on December 17, 2013.

20. The USPTO issued the '929 patent on May 9, 2017, naming BIAL - PORTELA as the assignee on the face of the patent.

21. Upon information and belief, BIAL - PORTELA is the owner of the '929 patent based on an assignment by David Alexander Learmouth, Gabriela Alexandra Grasa and Antonio Zanotti-Gerosa to Bial-Portela & C.A., S.A. for application no. 11/997,104 recorded at reel/frame 029941/0478 by a conveyance executed on March 13, 2008 and recorded on March 7, 2013.

22. The United States Patent and Trademark Office ("USPTO") issued the '747 patent on September 5, 2017, naming BIAL - PORTELA as the assignee on the face of the patent.

23. Upon information and belief, BIAL - PORTELA is the owner of the '747 patent based on (1) an assignment by Patricio Manuel Vieira Araujo Soares Da Silva to Bial-Portela & C.A., S.A. for application no. 14/240,847 recorded at reel/frame 032991/0598 by a conveyance executed on March 2, 2014 and recorded on May 29, 2014; and (2) a corrective assignment to correct the spelling of the assignee's name recorded at reel/frame 033433/0809 by a conveyance executed on March 2, 2014 and recorded on July 29, 2014.

24. The United States Patent and Trademark Office ("USPTO") issued the '954 patent on September 19, 2017, naming BIAL - PORTELA as the assignee on the face of the patent.

25. Upon information and belief, BIAL - PORTELA is the owner of the '954 patent based on an assignment by Patricio Manuel Vieira Ara Soares Da Silva to Bial-Portela & C.A., S.A. for application no. 12/257,240 is recorded at reel/frame 031840/0314 by a conveyance executed on September 1, 2009 and recorded on December 23, 2013.

26. Upon information and belief, Sunovion holds NDA No. 022416 for APTIOM® brand (hereinafter "APTIOM®") eslicarbazepine acetate oral tablets in 200, 400, 600, and 800 mg dosage strengths.

27. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") must follow when determining whether to approve for marketing brand and generic drugs.

28. Under the FFDCA, an applicant seeking to market a new brand drug must prepare a NDA for review by the FDA. See 21 U.S.C. § 355.

29. An NDA may include the patent number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

30. An NDA holder is required to submit to the FDA the patent number of each patent relevant to the drug for which the NDA was submitted to the FDA. The FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the Orange Book.

31. Upon information and belief, Sunovion caused the patents-in-suit (the '431, '135, '244, '929, '747 and '954 patents) to be listed in the Orange Book in connection with NDA No. 022416.

32. Jubilant filed Abbreviated New Drug Application No. 211219 ("Jubilant ANDA") seeking FDA approval to market its formulation of eslicarbazepine acetate oral tablets in 200, 400, 600, and 800 mg dosage strengths ("Jubilant ANDA Product") and referenced NDA No. 022416. As part of Jubilant's ANDA, Jubilant submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly called a "paragraph IV certification," that the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Jubilant's ANDA Product.

33. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), on January 15, 2018, Jubilant sent a Notice Letter to Bial notifying Bial that Jubilant had submitted ANDA No. 211219 for eslicarbazepine acetate oral tablets, 200, 400, 600, and 800 mg, and that the ANDA contained a paragraph IV certification that the patents-in-suit are invalid, unenforceable and/or will not be infringed by Jubilant's ANDA Product ("Jubilant's Notice Letter").

34. Jubilant's Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 211219 so that Bial could obtain more information if desired to determine whether Jubilant's ANDA Product would infringe any valid and enforceable claim of the patents-in-suit, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

35. Upon information and belief, Jubilant's Notice Letter was received by Janssen no later than January 18, 2016.

36. On March 1, 2018, Plaintiffs/Counterclaim-Defendants Bial sued Jubilant, alleging infringement of the patents-in-suit. There has been and is now an actual and justiciable

controversy between Jubilant and Bial as to whether the drug products described in ANDA No. 211219 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents-in-suit.

37. Jubilant and Plaintiffs/Counterclaim-Defendants have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the patents-in-suit. The patents-in-suit effectively delay FDA approval of the drug products described in ANDA No. 211219.

COUNT I

(Declaratory Judgment of Non-Infringement of the '431 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '431 Patent)

38. Jubilant repeats and incorporates by reference Paragraphs 1-37 of its Counterclaims as if fully set forth herein.

39. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '431 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '431 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

40. In Jubilant's Notice Letter, Jubilant provided reasons sufficient to show that Jubilant's ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the '431 patent.

41. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '431 patent.

42. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '431 patent.

COUNT II

(Declaratory Judgment of Non-Infringement of the '135 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '135 Patent)

43. Jubilant repeats and incorporates by reference Paragraphs 1-42 of its Counterclaims as if fully set forth herein.

44. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '135 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '135 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

45. In Jubilant's Notice Letter, Jubilant provided reasons sufficient to show that Jubilant's ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the '135 patent, and that the claims of the '135 patent are invalid.

46. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '135 patent.

47. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '135 patent, and/or that all claims of the '135 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

COUNT III

(Declaratory Judgment of Non-Infringement of the '244 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '244 Patent)

48. Jubilant repeats and incorporates by reference Paragraphs 1-47 of its Counterclaims as if fully set forth herein.

49. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '244 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by

ANDA No. 211219 and that all claims of the '244 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

50. In Jubilant's Notice Letter, Jubilant provided reasons sufficient to show that Jubilant's ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the '244 patent.

51. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '244 patent.

52. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '244 patent.

COUNT IV

(Declaratory Judgment of Non-Infringement of the '929 Patent by Jubilant's ANDA Product and Declaratory Judgment of Invalidity of the '929 Patent)

53. Jubilant repeats and incorporates by reference Paragraphs 1-52 of its Counterclaims as if fully set forth herein.

54. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '929 patent will be infringed by the manufacture, use, sale,

offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '929 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

55. In Jubilant's Notice Letter, Jubilant provided reasons sufficient to show that Jubilant's ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the '929 patent, and that the claims of the '929 patent are invalid.

56. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '929 patent.

57. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '929 patent, and/or that all claims of the '929 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

COUNT V

(Declaratory Judgment of Non-Infringement of the '747 Patent by Jubilant's ANDA Product, Declaratory Judgment of Invalidity of the '747 Patent and Declaratory Judgment for Correction of Improper Use Code)

58. Jubilant repeats and incorporates by reference Paragraphs 1-57 of its Counterclaims as if fully set forth herein.

59. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the '747 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 and that all claims of the '747 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

60. In Jubilant's Notice Letter, Jubilant provided reasons sufficient to show that Jubilant's ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the '747 patent, and that the claims of the '747 patent are invalid.

61. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the '747 patent.

62. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '747 patent, and/or that all claims of the '747 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

63. Plaintiffs/Counterclaim Defendants listed Use Code U-2041 "Treatment of Partial-Onset Seizures" in the Orange Book for the '747 patent.

64. The claims of the '747 patent all have absence-seizure limitations. The '747 patent distinguishes the two types of epilepsy: "Partial-onset seizures are a variety of epileptic seizure which affect only a part of the brain at onset. . . . In contrast, absence seizures, also known as petit mal seizures, are a form of generalized seizure, which affects the whole of the brain, producing abnormal electrical activity throughout both hemispheres and, typically, loss of consciousness."

65. The '747 patent claims require treatment of a patient suffering from or susceptible to absence seizures, and Use Code U-2041—directed to treatment of partial-onset seizures, not treatment of patients suffering from or susceptible to absence seizures—should be deleted from the '747 patent's Orange Book listing under NDA No. 211227, thereby permitting Jubilant to properly certify against the '747 patent.

66. Under 21 U.S.C. § 355(j)(5)(C)(ii)(I), Jubilant is entitled to an order: (1) finding that Plaintiffs/Counterclaim Defendants improperly filed with FDA Use Code U-2041 for the '747 patent in the Orange Book for NDA No. 211227 for APTIOM; and (2) requiring

Plaintiffs/Counterclaim Defendants to immediately request that FDA delete the use code listed for the ’747 patent in the Orange Book listing for NDA No. 211227 for APTIOM.

COUNT VI

(Declaratory Judgment of Non-Infringement of the ‘954 Patent by Jubilant’s ANDA Product and Declaratory Judgment of Invalidity of the ‘954 Patent)

67. Jubilant repeats and incorporates by reference Paragraphs 1-66 of its Counterclaims as if fully set forth herein.

68. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the ‘954 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Jubilant’s ANDA Product described by ANDA No. 211219 and that all claims of the ‘954 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

69. In Jubilant’s Notice Letter, Jubilant provided reasons sufficient to show that Jubilant’s ANDA Product described by ANDA No. 211219 does not infringe any valid claim of the ‘954 patent, and that the claims of the ‘954 patent are invalid.

70. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Jubilant’s ANDA Product described by ANDA No. 211219 will infringe any valid and enforceable claim of the ‘954 patent.

71. Jubilant is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Jubilant's ANDA Product described by ANDA No. 211219 will not infringe, directly or indirectly, any valid claim of the '954 patent, and/or that all claims of the '954 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

JURY DEMAND

72. Jubilant hereby demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Jubilant respectfully requests the Court enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

(a) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '431 patent has not infringed, and does not infringe, any valid and enforceable claim of the '431 patent;

(b) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '431 patent;

(c) A declaration that the claims of the '431 patent are invalid;

(d) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '135 patent has not infringed, and does not infringe, any valid and enforceable claim of the '135 patent;

(e) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '135 patent;

(f) A declaration that the claims of the '135 patent are invalid;

(g) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '244 patent has not infringed, and does not infringe, any valid and enforceable claim of the '244 patent;

(h) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '244 patent;

(i) A declaration that the claims of the '244 patent are invalid;

(j) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '929 patent has not infringed, and does not infringe, any valid and enforceable claim of the '929 patent;

(k) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '929 patent;

(l) A declaration that the claims of the '929 patent are invalid;

(m) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '747 patent has not infringed, and does not infringe, any valid and enforceable claim of the '747 patent;

(n) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '747 patent;

(o) A declaration that the claims of the '747 patent are invalid;

(p) A declaration that Use Code U-2041 be deleted from the '747 patent's Orange Book listing under NDA No. 211227 pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I);

(q) A declaration that Jubilant's submission of ANDA No. 211219 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '954 patent has not infringed, and does not infringe, any valid and enforceable claim of the '954 patent;

(r) A declaration that Jubilant's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Jubilant's ANDA Product described by ANDA No. 211219 does not, and will not, infringe any valid and enforceable claim of the '954 patent;

(s) A declaration that the claims of the '954 patent are invalid;

(t) A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Jubilant;

(u) A declaration that this case is exceptional in favor of Jubilant and awarding attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the inherent power of the Court;

(v) An award of costs and expenses;

(w) A declaration that Counterclaim-Defendants are not entitled to injunctive relief; and

(x) Such other and further relief as the Court may deem just and proper.

May 31, 2018

PRICKETT, JONES & ELLIOTT, P.A.

By: */s/ J. Clayton Athey*

J. Clayton Athey (Bar No. 4378)
John G. Day (Bar No. 6023)
1310 N. King Street
Wilmington, DE 19801
Telephone: (302) 888-6500
jcathey@prickett.com

Attorneys for Defendants Jubilant Life Sciences Limited, Jubilant Pharma Limited, Jubilant Generics Limited, Jubilant Life Sciences (USA) Inc., and Jubilant Cadista Pharmaceuticals Inc.

OF COUNSEL:

William D. Hare
MCNEELY, HARE & WAR LLP
5335 Wisconsin Ave, NW, Suite 440
Washington, DC 20015
Telephone: (202) 640-1801
bill@miplaw.com